DETAILED ACTION

1. This Office Action is responsive to the amendments filed 1/31/2012. Claim 38 is amended. **Claims 8-9, 11, 14, 38-40, and 51** remain pending and under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. **Claims 8-9, 11, 14, 38-40, and 51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stereotaxis (WO 00/07641) in view of Roberts et al (*Remote Control of Catheter Tip Deflection: An Opportunity for Interventional MRI*), further in view of Osadchy et al (US Pat No. 6266551).

6. In regards to **Claims 38 and 51**, Stereotaxis discloses a medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device 24, best seen in Figure 1;

a control system 22, 26 for controlling the position and/or orientation of the distal end 76 of the elongate medical device (p.5: 6-17, 31-38; p.6: 23-27; p.7: 6-26; p.8: 7-29), where the elastic property of the device are used in navigational control algorithms for guiding the device, i.e. the stiffness or elasticity of the device must be taken into account when determining the magnetic field intensity required to control the distal end of the device (p.7: 15-26; p.8: 37-39; p.9: 1-17);

an interface 36, 38, 40 for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device (p.4: 26-30; p.5: 6-10; p.6: 1-15, 24-40; p.7: 1-26); the interface sending instructions to the control system dependent in part upon the medical device's physical and geometric property information, including one or more cross-sectional areas of the device, and the elastic property of the device obtained from the memory device as explained above, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device (p.5: 1-5; p.8: 37-39; p.9: 1-17).

7. However, Stereotaxis does not disclose one or more cross sectional areas of the elongate device used in navigational control algorithms for guiding the device. Roberts et al teach that the control of an analogous elongate flexible medical device, i.e. catheter, is affected by the torque experienced by said medical device from the magnetic field, wherein the torque is directly proportional to the cross-sectional area of the coil that is wound around the tip of the device and is thus considered a cross-sectional area of the device, see equation 1 and 2 (p.1091 R column – effective area of coil). Roberts et al further teach that the device torque required to deflect the tip is directly proportional to E, Young's modulus, see equation 4 (p.1092 Materials and Methods). While Roberts et al pick a specific value to use in their calculations, one of ordinary skill in the art would know that the determination of Young's modulus requires the cross-sectional area of the object through which the force is applied, i.e. the elongate medical device, for example see http://en.wikipedia.org/wiki/Young's_modulus. Therefore, Roberts et al teach another example of using a cross-sectional area of the device. It is further noted that applicant's disclosure does not specifically set forth what is encompassed by the cross-sectional area of the device besides what is claimed.

8. Since torque and magnetic moment are essential variables to the navigational control of said analogous elongate device, and because cross-sectional area is integral to said calculations as taught by Roberts et al above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Stereotaxis to use said cross sectional area of the elongate device as defined above in the navigational control algorithms of the device as taught by Roberts et al to advantageously take into account a pertinent variable directly proportional to the amount of torque needed for navigation.

9. However, Stereotaxis and Roberts et al do not disclose a memory device provided on the flexible medical device that includes the information on the physical and geometric properties including one or more cross sectional areas of the elongate device and an elastic property of the elongate medical device that are relevant to navigational control of the device as described above. Osadchy et al disclose an analogous catheter system comprising a memory device 90 on an elongate flexible medical device 20 that includes information on the physical and geometric properties of the medical device, i.e. the position and orientation of distal tip 26 relative to coils 60, 62, 64 as well as information regarding the position of said coils or the gains of the coils (Col.2: 1-45, 65-66; Col.3: 1-4; Col.7: 21-29), to provide effective proper medical device identification before use (Col.17: 34-46).

10. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stereotaxis as modified by Roberts et al to include a memory device provided on the flexible medical device that includes the information on the physical and geometric properties such as one or more cross sectional areas of the elongate device and an elastic property of the elongate medical device that are relevant to navigational control of the device as described above, as taught by Osadchy et al, to ensure that such pertinent identifying information is provided for each particular flexible medical device before use for improved navigation and safety.

11. In regards to **Claim 39**, Stereotaxis discloses the at least one software program controls navigation by employing a computational model of flexible device physics (abst).

12. In regards to **Claim 40**, Stereotaxis in combination with Roberts et al and Osadchy et al disclose the memory device includes storing unique device identification information for the elongate flexible medical device, and wherein the interface includes a database of unique device identification information and corresponding device properties, and wherein the instructions sent to the control system take into account the device properties determined from the database (Osadchy et al Col.17: 33-46).

13. In regard to **Claims 8-9**, Stereotaxis in combination with Roberts et al and Osadchy et al disclose the invention above including Osadchy et al disclosing the memory contains unique identifying information about the type of device, but do not expressly disclose the interface includes a database of the unique identifying information of the type of devices with which the interface is intended to operate. Osadchy et al disclose an analogous catheter system comprising an electronic interface 36, 38, 40 for selectively operating the navigation device for selectively controlling the orientation of the distal end of the elongate flexible medical device, the electronic interface comprising a processor in computer 26 and including at least one software program, wherein the interface provides actuation instructions to the navigation device for controlling the distal end of the device (p.4: 26-30; p.5: 6-10; p.6: 1-15, 24-40; p.7: 1-26), which instructions take into account the physical and geometric properties of the elongate medical device (p.5: 1-5; p.8: 37-39; p.9: 1-17), and disclose the interface includes a database of the unique identifying information of the type of devices with which the interface is intended to operate (Col.17: 33-46).

14. In regards to **Claim 11**, Osadchy et al disclose the interface includes a plurality of programs, each adapted for use with a different type of elongate flexible medical device, each program operating only when an electronic identification device for the particular type of elongate flexible medical device is present (Col.5: 50-62).

15. In regards to **Claim 14**, Osadchy et al disclose the interface 36 tracks elapsed time of use of the identified elongate flexible medical device 20 and invalidates use of the identified elongate flexible medical device when the elapsed time exceeds a pre-defined limit (Col.17: 55-65; Col.18: 46-55).

16. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stereotaxis as modified by Roberts et al and Osadchy et al such that the interface includes a database of the unique identifying information of the type of devices with which the interface is intended to operate, only operating when an electronic identification device for the particular type of elongate flexible medical device is present, and tracks elapsed time of use of the identified elongate flexible medical device and invalidates use of the identified elongate flexible medical device when the elapsed time exceeds a pre-defined limit, as taught by Osadchy et al, to effectively implement safety measures to ensure that only a properly calibrated device can be used on the patient and to prevent use after the medical device has passed its expected lifespan.

Response to Arguments

17. Applicant's arguments filed 1/31/2012 have been fully considered but they are not persuasive. Applicant contends that Osadchy et al do not teach the data stored to determine "how" to move the distal tip to a particular location, but only how to more accurately determine where the tip is. However, this is not found persuasive because it appears that applicant is attempting to read Claim 38 more narrowly than is claimed. It is noted that Claim 38 merely recites "the interface sending actuation instructions to the control system *dependent in part upon* the medical device's physical and geometric property information," and "the physical and geometric properties of the device *are used* in navigational control algorithms for guiding the device" [emphasis added]. It is noted that said recitations do not specify *how* the physical and geometric properties must be taking into account/used for said navigational control and actuation, i.e. that said control and actuation is limited to information regarding "how to move," vs. "where." As elaborated in previous Office Actions, it is submitted that one of ordinary skill in the art would recognize the need to determine the actual position of the tip for proper navigation of the elongate medical device. It is common sense to one of ordinary skill in the art that navigation requires precise knowledge of the start point as well as the end point of any device. From there, one of ordinary skill in the art would thus be reasonably led to include such determination into the navigation device of Stereotaxis and subsequently provide actuation instructions taking into account the actually position of the tip, which is determined by Osadchy et al above, for reasons such as taking into account the differences in actual tip position influenced by the number of the magnetically responsive elements, spacing therebetween, and dimension, etc. Furthermore, it is noted that Osadchy et al teach calibration data may be stored

in the elongate medical device necessary as necessary for the steering of the device (Col.19: 47-50). Thus, it is believed that Osadchy et al are not only aware of the need of using various physical and geometric properties of the elongate medical device as essential in navigating the device, but also teach the advantages of such from specific properties such as the number of the magnetically responsive elements, spacing therebetween, and dimension, wherein Roberts et al is used to teach the utility of cross-sectional area in navigational control and actuation as previously explained. It is also noted that applicant's remarks regarding the use of Osadchy et al appear to have been affirmed in favor of the examiner in the previous appeal brief, for example on p.6-7 of the BPAI decision dated 5/31/2011. Therefore, the above rejection is maintained.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736